

REMARKS

Upon receipt of the Office Action, mailed May 1, 2008, Claims 1, 3, 5-6 and 8-74 were currently pending. Claims 16-56 were previously withdrawn from consideration as being directed to non-elected subject matter. Claims 1, 3, 5-6, 8-15 and 57-74 are rejected herein as discussed in more detail below. Reconsideration of the claimed subject matter in view of the following remarks is respectfully requested.

Third Supplemental Information Disclosure Statement

Applicants note that the Examiner had crossed-out Reference A1 in the Third Supplemental Information Disclosure Statement submitted on February 15, 2008, without providing any reasons why the reference was not considered by the Examiner.

Accordingly, Applicants submit herewith a Fourth Supplemental Information Disclosure Statement to bring to the attention of the Examiner the previously crossed-out Reference. This reference is from the European Pharmacopoeia, 3rd Edition, 1997, pages 1301-1302 and discloses solutions for peritoneal dialysis. Consideration of this reference by the Examiner is respectfully requested.

Rejection of Claims 1, 3, 5, 6, 8-15 and 57-74 under 35 U.S.C. § 112, ¶ 1

The Examiner has rejected Claims 1, 3, 5, 6, 8-15 and 57-74 under 35 U.S.C. § 112, ¶ 1, for lack of enablement. In particular, the Examiner contends that:

*[T]he specification, while being enabling for a "dialysate precursor composition comprising a citrate at concentration ranging from about 20 to about 900mEq/L; a buffering anion selected from acetate and/or lactate; water; chloride at a concentration ranging from about 1,000 to about 7,000 mEq/L; at least one physiologically-acceptable cation; and a therapeutically effective amount of **specific form of iron**", does not reasonably provide enablement [of] "a dialysate precursor composition comprising citrate at a concentration ranging [sic] from about 20 to about 900mEq/L; a buffering anion selected from acetate and/or lactate; water; chloride at a concentration ranging from about 1,000 to about 7,000 mEq/L; at least one physiologically-acceptable cation; and a therapeutically effective amount of **iron**." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.*

The Examiner considered the enablement issue in view of the following Wands factors (see *In re Wands*, 8 USPQ2d 1400).

Nature of the Invention

The Examiner contends that all of the rejected claims are drawn to a dialysate precursor composition comprising citrate at a concentration ranging from about 20 to about 900mEq/L; a buffering anion selected from acetate and/or lactate; water; chloride at a concentration ranging from about 1,000 to about 7,000 mEq/L; at least one physiologically-acceptable cation; and a therapeutically effective amount of iron, and further contends that the nature of the invention is extremely complex in that it encompasses the actual dialysate precursor composition such that the composition comprises iron.

Applicants respectfully dispute this contention. Not all of the rejected claims require the presence of water and/or a therapeutically effective amount of iron. Claims 61-67 are specifically directed to a "dry" dialysate precursor composition which does not comprise water or a therapeutically effective amount of iron.

Breadth of the Claims

The Examiner contends that the complex nature of the claims is greatly exacerbated by breadth of the claims in that the claims "encompass **any types of iron**" in the dialysate precursor composition, each of which may or may not be addressed by the administration of the claimed composition.

Applicants respectfully dispute this contention. One of ordinary skill in the dialysis field would easily recognize from the teachings of the specification that the "type" of iron contemplated by the claims is the type of iron which would be physiologically compatible with the well-being of the patient. Specific examples of such "types" of iron are listed on page 21 of the specification.

Guidance of the Specification

The Examiner contends that the guidance provided by the specification as to how one would administer the claimed composition with iron to formulate a dialysate precursor composition is minimal. The Examiner further contends that all of the guidance provided by the specification is directed towards a specific type of iron (e.g. ferric lactate).

Applicants respectfully dispute this contention. The specification provides detailed description on how to prepare the claimed dialysate precursor compositions, which are used in the standard three-stream dialysis process to produce a final dialysate composition. The concentrations of the various ingredients of the dialysate precursor compositions are described

in sufficient detail that one skilled in the dialysis art, particularly with respect to the standard process of mixing the various dialysate components (i.e., the dialysate precursor composition component, the bicarbonate component and water), would easily be able to use the invention without undue experimentation. In a similar manner, one skilled in the dialysis field would easily be able to determine without undue experimentation what a "therapeutically effective amount of iron" would be for such a dialysate precursor composition. As noted in the specification on page 21, an iron concentration in the final dialysate ranging from 0.1 to 300 micrograms/deciliter would be considered by the skilled artisan as a suitable "therapeutic amount". One skilled in the dialysis field could easily extrapolate the suitable concentration of iron in the final dialysate disclosed in the specification to the desired concentration of iron in the claimed dialysate precursor compositions.

Working Examples

The Examiner contends that all of the working examples provided by the specification are directed toward inclusion of the specific iron form rather than any iron.

Applicants respectfully dispute this contention. Given that the claims must be read in light of the specification, Applicants submit that one skilled in the art would easily recognize that the term "iron" as used in the claims is not directed to "any iron", but rather to any form of iron that is compatible to the well-being of the patient, particularly in view of the teaching on pages 20-21 of the specification as to which forms of iron are considered to be compatible.

State of the Art

The Examiner notes that the state of the art with regard to a dialysate precursor composition comprising any type of iron is underdeveloped. In particular, the Examiner notes that there do not appear to be any examples or teachings in the prior art wherein any type of iron was included in a dialysate precursor composition. The Examiner further contends that it would be highly speculative that any type of iron would work as a precursor dialysate composition for as a dialysate composition in view of the teachings of PCT Published Patent Application WO 98/06482A1 ("Ash") which discloses that iron dextran causes severe allergic reactions, fever and rashes during injection and that only about half of iron in the iron dextran is bio-available after intravenous injection for red cell production and that ferric gluconate is another macromolecular iron complex requiring a great deal of time and skill for administration.

Applicants respectfully dispute this contention. Applicants note the afore-mentioned problems with iron dextran and ferric gluconate disclosed in Ash are associated with the *intravenous* administration of these macromolecular iron complexes to a patient, and not necessarily to the inclusion of these iron complexes in a dialysate or a dialysate precursor composition. In fact, Applicants respectfully submit that the disclosure of Ash of an iron-containing dialysate composition is an example of the knowledge that one skilled in the dialysis art would be expected to have in being able to practice the instantly claimed invention without any undue experimentation.

Predictability of the Art

The Examiner contends that the lack of significant guidance from the specification or prior art with regard to inclusion of any types of iron makes practicing the claimed invention unpredictable in terms of the utilization of any type of iron.

Applicants respectfully dispute this contention. As noted above, the specification provides ample guidance as to the form of iron contemplated to be used in the claimed dialysate precursor compositions of the invention. Furthermore, as noted above, the disclosure of Ash specifically teaches the inclusion of several forms of iron in dialysate compositions. Although the dialysate compositions disclosed in Ash do not contain citrate, one skilled in the art, having knowledge of the teachings of Ash, would reasonably expect that the dialysate precursor compositions of the instant application could be successfully used in the formation of a final dialysate composition.

The Amount of Experimentation Necessary

The Examiner contends that:

In order to practice claimed invention, one of skilled in the art would have to first envision a combination of appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system for one of the claimed iron and test the combination in the model system to determine whether or not the combination is effective for a dialysate composition. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art [with] regard to inclusion of any type of iron, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance from the specification of prior art regarding utilization of any iron, the entire, unpredictable process would have to be repeated until successful. Therefore, it would require

undue, unpredictable experimentation to practice the claimed invention of inclusion of iron to formulate a precursory dialysate precursor.

Therefore, a dialysate precursor composition comprising citrate at a concentration ranging from about 20 to about 900mEq/L; a buffering anion selected from acetate and/or lactate; water; chloride at a concentration ranging from about 1,000 to about 7,000 mEq/L; at least one physiologically-acceptable cation; and a therapeutically effective amount of iron is not considered to be enabled by the instant specification.

Applicants respectfully dispute this contention. The test for enablement is whether one reasonably skilled in the art could make or use the claimed invention from the disclosure of the specification coupled with the information known in the art without undue experimentation. The key to any enablement issue is what is disclosed in the specification as to how to make and use the invention and what would be considered "undue experimentation" by one skilled in the art. As noted above, the specification clearly discloses to one skilled in the dialysis art as to which form of iron could be used in the claimed dialysate precursor compositions. Furthermore, the teachings of Ash, as noted above, would disclose to one skilled in the dialysis art additional specific forms of iron not specifically disclosed in the specification which one could use in practicing the invention. One skilled in the dialysis art, in view of these disclosures, would have reasonable expectation that any of these forms of iron could be used in the claimed dialysate precursor compositions in order to achieve the desired result. Furthermore, as noted above, the specification is quite clear on page 21 as to how much iron is considered a therapeutically effective amount in the final dialysate composition (between 0.1 to 300 micrograms/deciliter), which one skilled in the art could easily extrapolate to determine the corresponding amount to be used in the claimed dialysate precursor compositions.

In view of these teachings, Applicants respectfully submit that the specification unequivocally teaches a person reasonably skilled in the dialysis art as to which form of iron could be used in the dialysate precursor compositions of the invention, as well as how much of iron should be included therein. Furthermore, one skilled in the art would not have to result in undue experimentation in order to use the claimed dialysate precursor compositions, given that hemodialysis methods are well-known. Accordingly, Applicants respectfully submit that Claims 1, 3, 5, 6, 8-15 and 57-74, particularly Claims 57-60 which are directed to specific forms of iron, are fully enabled by the specification and respectfully request the withdrawal of the rejection of these claims under 35 U.S.C. § 112, ¶ 1.

Favorable consideration of the pending claims in view of the foregoing remarks and issuance of an early Notice of Allowance are earnestly solicited.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,
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